

Remarks:

Applicant has carefully studied the non-final Examiner's Action mailed July 21, 2009. These explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

Status of the Claims

Claims 1, 2, 6, 8, 10, 21, 22, 25, 27 and 28 were pending in the Office Action mail dated July 21, 2009. None of the previously pending claims are amended, canceled or withdrawn in the present response. Therefore, claims 1, 2, 6, 8, 10, 21, 22, 25, 27 and 28 are currently pending and under examination.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 2, 6, 8, 10, 21, 22, 25, 27 and 28 stand rejected by the Office as allegedly being anticipated under 35 U.S.C § 102(b) by WO 98/43702 to Mathiesen et al. ("Mathiesen"). Applicant traverses the rejection of the claims 1, 2, 6, 8, 10, 21, 22, 25, 27 and 28 because the Mathiesen reference fails to teach each element of the claims under consideration.

Anticipation is the standard under which claims are evaluated for 35 U.S.C. 102 (a), (b) and (e).¹ "Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration"^{2,3} Furthermore, to find anticipation the identical invention must

¹ MPEP Section 2131 – Anticipation – Application of 35 U.S.C. 102 (a), (b) and (e).

² *W.L. Gore and Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983) (citing *Soundsciber Corp. v. United States*, 360 F.2d 954, 960, 148 USPQ 298, 301 (Ct. Cl.), *adopted*, 149 USPQ 640 (Ct. Cl. 1966)), *cert. denied*, 469 U.S. 851 (1984); See also *Carella v. Starlight Archery*, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir.), modified on reh'g., 1 USPQ 2d 1209 (Fed. Cir. 1986). *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984).

³ See also MPEP 2131 providing "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ...The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsisimilis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

be shown in as complete detail as is contained in the claim with the elements arranged as required by the claim.⁴ No words in a claim may be disregarded. “All words in a claim must be considered in judging the patentability of that claim against the prior art.”⁵ “During patent examination, the pending claims must be ‘given their broadest reasonable interpretation consistent with the specification.’”⁶ “The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.”⁷

The claims are drawn to “[a] method for facilitating the delivery of a desired molecule into a target tissue ...” The method includes the application of a continuous electric field in the range of 1mV/cm to 200V/cm to the target tissue for a duration such as between 200 ms and 20 minutes. (e.g. independent claims 1 and 21)

The Office asserts that Mathiesen teaches such a method. In particular, the Office asserts that “[s]pecifically, Mathiesen teaches injecting a DNA plasmid containing a beta-galactosidase gene into the muscle of rats and applying a single bipolar pulse of 25V for 5000 μ s (i.e., 500ms), resulting in the transfection of cells of the muscle tissue with the DNA plasmid (e.g., see Examples 5 and 6 on page 13, Figure 15, etc.)”⁸ The Office also excerpts claims 1-3 of Mathiesen. Claim 3 of Mathiesen is directed to “[t]he method of delivering a molecule of claim 2 wherein said bipolar pulse has a duration of between about 50 μ s and 5000 μ s.” Later on page 3 of the Office Action the office asserts that “Mathiesen clearly teaches administering 100 bipolar pulses for 2000 μ s (i.e., 200ms) (see Example 5 and Table 3, page 13).

Applicant does not dispute that Mathiesen refers to 5,000 μ s and/or 2,000 μ s. However, 5,000 μ s is not 500ms, it is 5ms. Similarly, 2,000 μ s is not 200ms, it is 2ms.

A μ s (microsecond) is equal to 10^{-6} seconds.⁹ A ms (millisecond) is equal to 10^{-3} seconds.¹⁰ Thus, there are 1000 μ s in 1 ms, not 10 μ s in 1 ms as indicated by the Office. Therefore, when Mathiesen refers to 5,000 μ s and/or 2,000 μ s, this refers to 5 ms and 2 ms,

⁴ Id.

⁵ *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

⁶ MPEP 2111 – Claim Interpretation – citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005).

⁷ MPEP 2111 – Claim Interpretation – citing *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)).

⁸ Office Action mail dated July 21, 2009 at page 3.

⁹ See for example the definition of “second” in Wikipedia at <http://en.wikipedia.org/wiki/Second>.

¹⁰ Id.

respectively. Clearly this does not meet the limitation of a duration “between 200 ms and 20 minutes...” as required by independent claims 1 and 21.

Accordingly, the Mathiesen reference fails to teach each element of the claims under consideration. It is therefore requested that the Office withdraw the rejection of claims 1, 2, 6, 8, 10, 21, 22, 25, 27 and 28 under 35 USC § 102(b) as being unpatentable over WO 98/43702 to Mathiesen et al.

Conclusion

For the reasons cited above, Applicant believes that claims 1, 2, 6, 8, 10, 21, 22, 25, 27 and 28 are patentable and in condition for allowance.

If the Office is not fully persuaded as to the merits of Applicant’s position, or if an Examiner’s Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,

SMITH & HOPEN

/michael m mcgaw/

By: _____

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CERTIFICATE OF ELECTRONIC TRANSMISSION TRANSMISSION
(37 C.F.R. 2.190(B))

I HEREBY CERTIFY that this Amendment L is being electronically transmitted to the United States Patent and Trademark Office through EFS Web on August 11, 2009.

/lauren reeves/

Date: August 11, 2009

Lauren Reeves